

Application No. 10,509,912

Attorney Docket: 0020-5301PUS1

REMARKS

Claims 20-34 are pending in the present application. Claims 20-34 have been rejected.

A typographical error has been corrected on page 5, line 13 of the specification.

Amended claims 20-23 and 30-34 are rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement. On pages 5-6 of the Office Action, the Examiner has stated that "only the structurally defined chemical compounds, but not the full breadth of the claims, meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant."

Amended claims 20 and 22 are rejected under 35 USC 102(b) as being anticipated by Harada et al. (Journal of Controlled Release, 2000, 69, pp 399-412, of record.)

Finally, amended claims 21 and 23-34 are rejected under 35 USC 103(a) as being unpatentable over Harada et al. (Journal of Controlled Release, 2000, 69, pp 399-412, of record) in view of Wall et al. '817 and in view of Wall et al ('072).

All of these rejections are respectfully traversed. Reconsideration and withdrawal thereof are specifically requested.

Rejection under 35 USC 103(a) (Unobviousness)

Harada et al. acknowledges that the Harada reference does not specifically disclose certain features of the invention claimed herein; page 11, second paragraph of the Office Action.

DDS-camptothecin which has a structure formed by binding a camptothecin compound with a polysaccharide (carboxymethylated dextran or pullulan) via a spacer such as a peptide like gly-gly-gly is neither disclosed nor suggested in view of the Wall et al references ('817 Patent

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and '072 Patent). Therefore, as a matter of fact, not only is a characteristic property of DDS-camptothecin having the polysaccharide as mentioned above diminished, but also the problem of the preparation (preservative stability of an aqueous solution or a lyophilized preparation, etc., and means for solving it are neither disclosed nor suggested in the references of (Wall et al.).

As is clear from the description of EP 1308171(see columns [004] to [005], and [0037] to [0038]), it has been known that with regard to DDS-camptothecin (hereinafter abbreviated as DDS-camptothecin A) which has a structure formed by binding a camptothecin compound with a polysaccharide such as dextran et al. directly or via a peptide-spacer, due to interaction between the camptothecin moiety and the polysaccharide moiety in the molecule, serious problems such as an increase of average molecular weight during preservation and a great decrease of re-dissolution on the lyophilized preparation will occur.

However, since a camptothecin derivative described in the Wall et al references, as mentioned above, does not have any polysaccharide moiety in its molecule, there is no room to induce the interaction between the camptothecin moiety and the polysaccharide moiety and therefore, such a problem and means for solving it could neither be disclosed nor be suggested in the Wall et al references.

Therefore, there is no rationality to combine the Harada et al reference with the Wall et al references in order to deny patentability of the subject matter of the amended claims.

It is clear that DDS-camptothecin A mentioned above more greatly resembles DDS-camptothecin related to the present invention than a camptothecin derivative (not having a polysaccharide) disclosed in the Wall et al references. Furthermore, it is described in EP1308171 that a filler such as a sugar or a sugar alcohol is essentially added to DDS-camptothecin A having a polysaccharide in order to maintain a preservative stability in its lyophilized preparation (by adding a filler to the interaction between the camptothecin moiety and the polysaccharide moiety).

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On the contrary, as shown in the ITO Declaration which has already been filed in the USPTO, the preparation of the present invention unexpectedly (in spite of the fact that such a filler mentioned above is not admixed) shows surprisingly excellent preservative stability properties as compared with a preparation containing such a filler. We believe that the preparation of the present invention having such an excellent effect would not be obvious over the Harada et al. reference in view of the Wall et al references.

Conclusion

Accordingly, it is believed that the rejections made under the provisions of 35 USC 112, 102 and 103 are obviated for the reasons as explained above. Favorable action is requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Raymond C. Stewart Reg. No. 21,066 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

By Raymond C. Stewart
Raymond C. Stewart
Registration No.: 21,066
BIRCH, STEWART, KOLASCH & BIRCH, LLP
8110 Gatehouse Road
Suite 100 East
P.O. Box 747
Falls Church, Virginia 22040-0747
(703) 205-8000
Attorney for Applicant